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United States Nuclear Regulatory Commission Region III 801 Warrenville Road

License No. 21-03429-04 Docket No. 030-13998 EA No. 93-281

Dear Mr. Axelson:

Lisle, IL 60532-4351

May 31, 1994

SUBJECT: NRC INSPECTION REPORT NO. 030-13998/93001(DRSS)

This document is in reference to your findings from the special safety inspection conducted at our facility June 8 and 9, 1993. Please find below our responses to the concerns raised.

 FAILURE TO INSTRUCT THE NUCLEAR MEDICINE TECHNOLOGIST IN THE SPECIFICS OF THE LICENSEE'S QMP AS REQUIRED BY 10 CFR 35.25

 (a) (1).

The previous Nuclear Medicine technologist (Steven Homan) did not understand the activity level correctly. He understood the QMP was required with activity greater than 30 mci (millicuries) when in fact the QMP is required over 30 uci (microcuries). Steve in turn told our medical physicist and RSO that we did not do therapy requiring the QMP which perpetuated the problem.

The Quality Management Program document was relatively new and unfamiliar to the staff and RSO. (January 27, 1992)

The loss of continuity as a result of multiple staff position changes contributed to the problem. The department manager left in May of 1992, the Nuclear Medicine technologist left in August of 1992, the back-up Nuclear Medicine technologist left in January of 1992. Medical Physics Consultants assigned a new physicist to Gratiot Community Hospital in July of 1992.

Thomas Abraham reviewed the QMP and was aware of the requirements. Minutes from the Fourth Quarter Radiation Safety Committee meeting indicate that he raised the question concerning administration of the QMP at that time. The assumption was made by the RSO and physicist that we were not exceeding the trigger level for using the QMP and miscommunication between Mr. Abraham and the physicist further delayed the resolution.

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Upon being made aware of our error, we promptly took appropriate corrective action. The most significant responses to this issue are as follows: 1. A technologist training document was instituted that must be read and signed prior to

document was instituted that must be read and signed prior to assuming duties at Gratiot Community Hospital. 2. A written test must be taken that assures understanding of the QMP. 3. A redesigned QMP checklist and Written Directives form were instituted. 4. Our physicist stepped up reviews from annually tc quarterly. 5. RSO directed that the technologist/physicist provide quarterly reviews of each therapy case.

2. FAILURE TO PREPARE A WRITTEN DIRECTIVE SIGNED AND DATED BY THE AUTHORIZED USER PRIOR TO THE ADMINISTRATION OF QUANTITIES GREATER THAN 30 MICROCURIES OF I-131 AS REQUIRED BY 10 CFR 35.32 (a)(1).

This omission stems from item 1 and corrective actions listed for item 1 are specific to this issue.

3. FAILURE TO DATE WRITTEN DIRECTIVES PREPARED BY THE AUTHORIZED USER PRIOR TO THE ADMINISTRATIONS OF QUANTITIES GREATER THAN 30 MICROCURIES OF I-131 AS REQUIRED BY 10 CFR 35.32 (a)(1) and 35.2.

The omission of the date is the result of item 1 as well. A training checklist and test has been instituted to assure full understanding and compliance with each of the requirements of the QMP.

## SUMMARY

Gratiot Community Hospital responded quickly and appropriately to each of the concerns found as a result of the NRC inspection of June, 1993. Also Gratiot Community's record with the NRC shows that we have not knowingly violated NRC regulations in the past and have responded quickly and appropriately when concerns have been brought forward.

The record shows that during a routine NRC inspection in February of 1992, there were no violations found.

Findings from the June 8-9, 1993 NRC inspection were immediately responded to as a result of the exit conference conducted by Mr. Mitchell on June 9, 1993. A compliance plan was drafted on June 10, 1993 which addressed every item voiced by Mr. Mitchell.

Before receiving the July 16, 1993 documentation from the NRC inspection (in which some of the items did not even appear), every item had been appropriately dealt with. Most items were corrected by June 17, and the entire list was completed by June 22, 1993.

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When making your determination with regard to escalated enforcement, we ask that you take into account our past record, our prompt response to concerns and the fact that the QMP is working very well with the changes put in place which includes a new Nuclear Medicine technologist certified by NMTCB and possessing a B.S. degree in Nuclear Medicine Technology. We feel we are operating a well managed Nuclear Medicine department and are confident that, if you were to visit us again, would find we are operating within NRC parameters.

Sincerely,

Don Pray Executive Vice President

DP:GM:ra

cc: Bob Baker, President Peter Boss, M.D., RSO Galen Miller, Radiology Manager